



STATEMENT OF EMERGENCY
201 KAR 2:350E

- (1) This emergency administrative regulation is being promulgated to comply with KRS 315.518(1), 315.520(4). KRS 315.518(1), 315.520(4) requires that the board establish by administrative regulation the requirements for an applicant to obtain a license to operate as a home medical equipment provider. This action must be taken on an emergency basis in accordance with KRS 13A.190(1)(a) to meet a deadline for the promulgation of an administrative regulation that is established by state law.
- (2) Failure to enact this administrative regulation on an emergency basis in accordance with KRS 13A.190(1)(a) compromises the board's ability to comply with the provisions of KRS 315.518(1), 315.520(4) on the date that the Act becomes effective as law, thereby interfering with the board's ability to act quickly in its efforts to address the prescription drug epidemic.
- (3) This emergency administrative regulation shall be replaced by an ordinary administrative regulation to be concurrently filed with the Regulations Compiler.
- (4) The ordinary administrative regulation is identical to this emergency administrative regulation.

Steve Beshear
Governor

Joel Thornbury, President
Kentucky Board of Pharmacy

1 GENERAL GOVERNMENT CABINET

2 KENTUCKY BOARD OF PHARMACY

3 (New Emergency Administrative Regulation)

4 201 KAR 2:350E. Home Medical Equipment Service Providers.

5 RELATES TO KRS 315.512, 315.514, 315.518, 314.520

6 STATUTORY AUTHORITY: KRS 315.191, 315.518(1), (4), 315.520(4)

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191 authorizes the Board
8 of Pharmacy to promulgate administrative regulations governing home medical
9 equipment and service providers. This administrative regulation establishes the
10 minimum requirements for the licensing of a home medical equipment service provider.

11 Section 1. General Requirements. (1) A home medical equipment company engaged in
12 providing services in the Commonwealth shall apply for a license from the board in
13 accordance with KRS 315.518 and this administrative regulation.

14 (2) An agent or employee of a licensee shall not be required to obtain a license if the
15 agent or employee is acting in the usual course of business or employment.

16 (3) A license shall not be issued or renewed unless the applicant demonstrates or
17 continues to demonstrate acceptable operational procedures, including:

18 (a) Adequate maintenance and storage conditions to ensure proper lighting, ventilation,
19 temperature, and humidity control, sanitation, space, and security;

1 (b) Establishing and providing records of annual continuing education for personnel
2 engaged in the delivery, maintenance, repair, cleaning, inventory control, and financial
3 management of home medical equipment and services; and

4 (c) Providing accurate and precise records of all goods shipped or received including
5 source of receipt, date, quantity, itemized description, and any other information pertinent
6 to the transaction.

7 (4) An applicant for a home medical equipment license shall prepare and adopt a policy
8 and procedure manual that sets forth a detailed description of how the:

9 (a) Operation will comply with applicable federal, state, or local laws or administrative
10 regulations; and

11 (b) Licensees will maintain the premises so that the home medical equipment remains
12 secure.

13 Section 3. Sanitation and safety requirements. (1) An applicant for a home medical
14 equipment license located in the Commonwealth of Kentucky shall be inspected by the
15 board prior to the issuance of the license.

16 (2)(a) The designated business area shall be used exclusively for the sale, rental, and
17 distribution of home medical equipment.

18 (b) Repairs and cleaning shall be done in a confined, properly ventilated area.

19 (c) All areas shall be adequately lighted and all areas kept in a clean and sanitary manner.

20 (3) A home medical equipment supplier shall comply with the maintenance and cleaning
21 requirements established in this subsection. A home medical equipment supplier shall:

22 (a) Maintain documents demonstrating that a function and safety check of equipment was
23 performed prior to set up;

- 1 (b) Maintain an established protocol for cleaning and disinfecting equipment which
- 2 addresses both aerobic and anaerobic pathogens;
- 3 (c) Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used
- 4 in cleaning and disinfecting procedures;
- 5 (d) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty,
- 6 and contaminated equipment;
- 7 (e) Clean and disinfect equipment according to manufacturer's specifications;
- 8 (f) Instruct the patient on proper cleaning techniques as specified by the manufacturer;
- 9 and
- 10 (g) Perform routine inspection, service, and maintenance of equipment located in the
- 11 patient's or customer's home according to manufactures' specifications.
- 12 (4) The supplier's services shall be available twenty-four (24) hours, seven (7) days per
- 13 week if it is essential to the maintenance of life or lack of service might reasonably cause
- 14 harm.
- 15 (5) The supplier shall:
- 16 (a) Demonstrate that each piece of equipment has been checked, is free of defects, and
- 17 operates within the manufacturer's specifications;
- 18 (b) Maintain documentation, which shall include the following:
- 19 1. The type of equipment;
- 20 2. The manufacturer;
- 21 3. The model number;
- 22 4. The serial number;
- 23 5. The date of repair;

- 1 6. The specific repair made; and
- 2 7. The name of the person or company performing the repair;
- 3 (c) Refrain from modifying equipment to the extent that the modification might
- 4 reasonably cause harm;
- 5 (d) Maintain all electrical components so that they do not present fire or shock hazard;
- 6 (e) Ensure that all appropriate warning labels or labeling, including tags, are present on
- 7 the equipment provided;
- 8 (f) Document all equipment serial numbers and model numbers to ensure that equipment
- 9 can be retrieved if a recall is initiated; and
- 10 (g) Affix an identifying label that contains the name of the provider, address, and phone
- 11 number.
- 12 (6) The supplier shall implement and maintain a written procedure at each location for
- 13 handling complaints and problems. The procedure shall include a complaint file
- 14 documenting complaints and problems and resolution of the complaints and problems.
- 15 Section 4. License Fee; Renewals. (1) A home medical equipment and services provider
- 16 shall be licensed by the board prior to engaging in providing home medical equipment
- 17 and services in the Commonwealth.
- 18 (2) An applicant shall submit:
- 19 (a)1. A completed Application for Home Medical Equipment License; and
- 20 2. The initial application fee established by 201 KAR 2:050, Section 1(21); or
- 21 (b)1. A completed Application for Home Medical Equipment License Renewal; and
- 22 2. The renewal application fee established by 201 KAR 2:050, Section 1(22).

1 Section 5. Incorporation by Reference. (1) The following material is incorporated by
2 reference:

3 (a) “Application for Home Medical Equipment License”, Form 1, 07/2012; and

4 (b) “Application for Home Medical Equipment License Renewal”, Form 2, 07/2012.

5 (2) This form may be obtained, inspected, or copied, subject to applicable copyright law,
6 at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes
7 Street, Frankfort, Kentucky, 40601, Monday through Friday, 8:00 a.m. to 4:30 p.m.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:350E. Home Medical Equipment

Contact person: Michael Burleson

(1) Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation allows a home medical equipment provider to be licensed if the applicant meets the requirements of this administrative regulation.
- (b) The necessity of this administrative regulation: This regulation is necessary to comply with HB 282.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: The regulation is in conformity with the authorizing statute that authorizes the board to promulgate administrative regulations that establishes the requirements for a home medical equipment provider.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation will set the requirements for a home medical equipment provider to obtain a license.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation:
- (b) The necessity of the amendment to this administrative regulation:
- (c) How the amendment conforms to the content of the authorizing statutes:
- (d) How the amendment will assist in the effective administration of the statutes:

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates less than 500 home medical equipment providers annually will be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

- (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: An applicant will be able to obtain a home medical equipment license to provide home medical equipment to patients in the Commonwealth.
- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Each applicant will be required to pay a fee of \$200 for initial licensure and a renewal fee of \$200 annually.

- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Home medical equipment providers will be able to be licensed to provide home medical equipment to patients in the Commonwealth.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: Unknown: there will be cost of completing inspections by the board inspectors (time and travel) and cost of board attorney in review and prosecuting cases of home medical equipment providers.

(b) On a continuing basis: Unknown: there will be costs of completing inspections and cost of board attorney in review and prosecuting cases of home medical equipment providers.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The funds for implementation and enforcement will come from the fees collected for the initial application fee and annual renewal fees.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No fees will be increase. Funding will be necessary to complete the inspections and attorney fees.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation establishes fees for initial licensure and annual renewals.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering was not applied as the regulation is applicable to home medical equipment provider.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 201 KAR 2:350E

Contact Person: Michael Burleson

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. 2012 RS HB 282 and KRS 315.191 requires or authorizes the action taken by this administrative regulation.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? \$80,000.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? \$80,000

(c) How much will it cost to administer this program for the first year? Unknown

(d) How much will it cost to administer this program for subsequent years? Unknown

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

Revenues: The Board anticipates yearly revenue of \$80,000 (400 applicants x \$200)

Expenditures: The Board inspectors will be required to inspect the home medical equipment facilities and there will be travel costs; software upgrade, and board attorney fees for prosecuting complaints against home medical equipment providers.

SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

201 KAR 2:350. Home Medical Equipment License and Renewal

“APPLICATION FOR HOME MEDICAL EQUIPMENT” (7/2012)

This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky, 40601, 8:00 a.m. to 4:30 p.m. This material may also be inspected or copied on the Board’s website: www.pharmacy.ky.gov. If you have questions, please contact the Board at 502-564-7985.

“Application for Home Medical Equipment License” Form 1 (7/2012)

- (a) This application is for initial license for a home medical equipment provider. This application requires the name, address, phone number, fax number, email address, the type of ownership, information on the owners/officers- including name, business and home addresses and phone numbers, social security number, birth date, hours of operation, and signature required by the owner.
- (b) 2012 RS HB 282 and KRS 315.191 provide the board authorization to promulgate this regulation.
- (c) This application is two (2) pages.

“Application for Home Medical Equipment License Renewal” Form 2 (7/2012)

- (a) This application is for renewal of a home medical equipment provider. This application requires the name, address, phone number, fax number, email address, the type of ownership, information on the owner/officers-including name, business and home address and phone numbers, social security number, birth date, and the signature of the owner.
- (b) 2012 RS HB 282 and KRS 315.191 provide the board authorization to promulgate this regulation.

This application is one (1) page.